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09/308,955	05/27/1999	KRISTIN M. LUNDY	PC9808A	6904

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/308,955	Applicant(s) LUNDY ET AL.	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5 and 8-36* is/are pending in the application.

4a) Of the above claim(s) *34-36* is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *4,5 and 8-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al., 3,896,145. (Already of record).

2. Claims 5, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Berger et al., 3,896,145.

3. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holtsinger et al. or Vasseur et al., or Berger et al, supra.

4. Applicant is advised that should claim 21 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 21 and 26 are identical in scope.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received Jul. 2, 2002.

Claims 2, 3, 6 and 7 are cancelled. New claims 27-36 are added. Claims 1, 4, 5, 8-36 are currently pending.

The following rejections **are withdrawn** in view of Applicant's amendment and the remarks contained therein:

5. Claims 1, 2, 5, 6, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Holtsinger et al. or Vasseur et al.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holtsinger et al. or Vasseur et al. or Berger et al, supra.

7. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Holtsinger et al. or Vasseur et al. (already of record).

8. Claims 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holtsinger et al. and Vasseur et al., supra.

However, Applicant's arguments traversing (1) the previous rejection of claims 24-25 under 35 U.S.C. 103(a) over Berger et al., 3,896,145.(set forth in paragraph 12 of the office action mailed Dec. 31, 2001) ; (2) the previous rejection of claims 5, 8, 9 under 35 U.S.C. 102(b) as being anticipated by Berger et al., 3,896,145; and (3) the previous rejection of claims 10-14 under 35 U.S.C. 103(a) over Holtsinger et al. or Vasseur et al. or Berger et al (set forth in paragraph 10 of the office action mailed June 5, 2001 and maintained in the office action mailed Dec. 31, 2001), have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office actions mailed June 5, 2001 and Dec. 31, 2002 with the following additional comment:

Concerning the rejection of claims 24-25, it is essentially Applicant's position that Berger et al. do not disclose the sub-genus of compounds as currently claimed (page 19 of Applicant's response). Said argument has been considered but is not found persuasive. Applicant has not specifically pointed out the distinctions between the Berger patent and the claimed invention. The reply has not presented arguments pointing out the specific distinctions believed to render the claims patentable over Berger et al. Absent such specific distinctions, the Examiner maintains that Berger et al. disclose pharmaceutical compositions useful as anti-inflammatory, analgesic and anti-rheumatic agents, the compositions comprising carbazole compounds which read on Applicant's claimed generic formula (I). The compositions are useful for oral or parenteral administration and may be in the form of tablets, capsules, suppositories, suspensions, solutions and emulsions. Please see col. 4-col. 7; col. 14, lines 1-12; col. 15, lines 8-24; claim 1.

Berger et al. do not teach a pharmaceutical combination comprising the carbazole compounds and printed informational material; however, drugs are often packaged with printed material before being distributed in commerce and such a modification of known pharmaceutical compositions into packaged combinations with instructional material is not novel or unobvious and is well within the capability of the skilled artisan. Furthermore, such printed material does not further limit the structural aspects of the claimed composition but only serves to inform the user of the pharmaceutical composition's intended use and/or activity. Additionally, the use of (R) and (S)-enantiomers of the compounds would have been obvious to one of ordinary skill in the art not only because Berger suggests the use of enantiomers in the compositions but also

because it has been held that isomers of a racemic compound are expected to have differing activities; one isomer is expected to more active than others (optically active isomer substitution was held to be obvious). **See In re Anthony, 162 USPQ 594; In re Adamson, 125 USPQ 233.**

With respect to the rejections of claims 5, 8, 9 under 35 USC 102(b), Applicant argues that none of the features of claim 5 are disclosed by Berger et al. (see page 18 of Applicant's response).

Said argument has been considered but is not found to be persuasive.

Applicant has not specifically pointed out the distinctions between the Berger patent and the claimed invention. The reply has not presented arguments pointing out the specific distinctions believed to render the claims patentable over Berger et al. Absent such specific distinctions, the Examiner respectfully maintains that Berger et al. continue to teach the invention substantially as claimed. Specifically, Berger et al. teach pharmaceutical compositions useful as anti-inflammatory, analgesic and anti-rheumatic agents, the compositions comprising carbazole compounds which read on Applicant's claimed generic formula (I). Please see the definition for substituents "R2", R3", "R" and "R1". The compositions are useful for oral or parenteral administration and may be in the form of tablets, capsules, suppositories, suspensions, solutions and emulsions. Please see col. 4-col. 7; col. 14, lines 1-12; col. 15, lines 8-24.

In addressing the rejections of claims 10-14, the Examiner respectfully maintains that it would have been obvious to one of ordinary skill in the art to modify the compositions of Berger to combine an additional NSAID because NSAID's are known in the art to be useful as analgesic,

anti-inflammatory compounds as evidenced by Holtsinger or Vasseur. Modification to combine the anti-inflammatory, analgesic compounds of Berger with other NSAID's, all of which are known to be useful for the same purpose, would have been obvious to one of ordinary skill in the art in view of the fact that the courts have held that "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose" Kindly refer to In re Susi, 169 USPQ 423, 426 (CCPA 1971); In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Additionally, Applicant argues that claims 12-14 are novel and unobvious because the art does not disclose the claimed packages. Applicant contends that no art is offered to substantiate the Examiner's allegation of obviousness. However, the Examiner respectfully maintains that drugs are often packaged with printed material before being distributed in commerce and such an art-recognized modification of known pharmaceutical compositions into packaged combinations with instructional material is not novel or unobvious and is well within the capability of the skilled artisan. Furthermore, printed material does not further limit the structural aspects of the claimed composition but only serves to inform the user of the pharmaceutical composition's **intended use and/or activity**.

New Ground of Rejection(s)

Applicant's amendment necessitated the following new ground(s) of rejection.

9. Newly submitted claims 34-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 34-36 are drawn to a

distinct method of identifying compounds requiring different methods steps and having different results.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

10. Claims 4, 5, 8, 11 are objected to because of the following informalities: in claim 4, line 27, after "hydroxychloroquine;" the term --and-- should be added. In claim 5, line 9, "ration" should read --ratio--. In claim 8, line 24, "sustaine" should read --sustained--. In claim 11, line 24, after "hydroxychloroquine;" the term --and-- should be added. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. Claims 4, 11, 15-23, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, page 4, line 19, the term "(anti-hypercholester-olemics)" renders the claim vague and indefinite because it is not clear whether the limitation(s) within the "( )" is part of the

claimed invention. The same applies to claim 11, page 8, line 19, wherein "(anti-hypercholesterolemics)" also appears. The metes and bounds of the patent protection desired is unclear.

12. Claim 15 recites the limitation "said drug" at page 9, line 15 . There is insufficient antecedent basis for this limitation in the claim.

13. Claims 16 and 17 recite the limitation "said drug" in line 3 . There is insufficient antecedent basis for this limitation in the claim.

14. Claim 18 recites the limitation "said drug" at page 11, line 8 . There is insufficient antecedent basis for this limitation in the claim.

15. Claims 19-20 recite the limitation "said drug" in line 3 . There is insufficient antecedent basis for this limitation in the claim.

16. Claim 21 recites the limitation "said drug" at page 12, line 15 . There is insufficient antecedent basis for this limitation in the claim.

17. Claims 22-23 recite the limitation "said drug" in line 3 . There is insufficient antecedent basis for this limitation in the claim.

18. Claim 26 recite the limitation "said drug" at page 15, in line 15 . There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holtsinger et al. or Vasseur et al. (already of record).

Holtsinger et al. teach a method of treating dogs suffering from degenerative joint disease, the method comprising administering to the dogs an effective amount (2.2 mg/kg) of carprofen. Results show that Carprofen is effective reducing the symptoms of the joint disease. Please see the abstract; page 141, "Materials and Methods".

Vasseur et al. disclose a method of treating dogs suffering from osteoarthritis, the method comprising administering to the dogs an effective amount (2.2 mg/kg) of carprofen. Results show that the dogs responded positively to the treatment. Please see the abstract; Discussion.

Holtsinger et al. or Vasseur et al. do not disclose administering non-racemic mixtures of carprofen such as the claimed (+)(S)-enantiomers; however, the individual isomers are obvious variants over the corresponding racemate because of their presence in the racemate. Moreover, the use of the (R) or (S)-enantiomers of carprofen would have been obvious to one of ordinary skill in the art because it has been held that isomers of a racemic compound are expected to have differing activities; one isomer is expected to more active than others (optically active isomer substitution was held to be obvious). **See In re Anthony, 162 USPQ 594; In re Adamson, 125 USPQ 233.**

Concerning the claimed concentrations of (+)(S) isomer (claims 28-33), since the anti-inflammatory results sought by Holtsinger or Vasseur and the isomers used were known and present in the racemate of Holtsinger or Vasseur, it is within the expected skills of one having ordinary skill in the relevant art to arrive at the optimum proportion of those isomers.

Concerning Applicant's arguments regarding Table 2 and the evidence of the "greater" functionality of the (S) enantiomer, the Examiner respectfully submits that such evidence does not appear to show unexpected results, but instead serves to support the Examiner's argument that isomers are expected to have differing activities, with one isomer being more active than others.

Conclusion

Claim 1 is free from the prior art.

Claims 4, 5, 8-33 are rejected.

Claims 34-36 are withdrawn from consideration.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Nov. 3, 2002

DWAYNE C. JONES
PRIMARY EXAMINER